Senate Amendment 3309

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Amend House File 882, as amended, passed, and reprinted by the House, as follows:

#1. Page 48, by inserting after line 26 the following:

<DIVISION ___

PROVISIONS RELATING TO THE PRACTICE OF PHARMACY

Sec. ___. Section 155A.3, subsection 11, Code 2005, is amended to read as follows:

11. "Dispense" means to deliver a prescription drug, device, or controlled substance to an ultimate user or research subject by or pursuant to the lawful prescription drug order or medication order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

Sec. ___. Section 155A.3, Code 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 22A. "Logistics provider" means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer or other owner of a drug, but does not take title to the drug or have general responsibility to direct its sale or other disposition.

Sec. ___. Section 155A.3, Code 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 23A. "Pedigree" means a recording of each distribution of any given drug or device, from the sale by the manufacturer through acquisition and sale by any wholesaler, pursuant to rules adopted by the board.

Sec. ___. Section 155A.3, subsection 33, paragraph b, Code 2005, is amended to read as follows:

b. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with ~~either~~ one of the following statements:

(1) Caution: Federal law prohibits dispensing without a prescription.

(2) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) Caution: Federal law restricts this device to sale by, or on the order of, a physician.

(4) Rx only.

Sec. ___. Section 155A.3, subsection 35, Code 2005, is amended to read as follows:

35. "Proprietary medicine" or "over=the=counter medicine" means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

Sec. ___. Section 155A.3, subsection 38, Code 2005, is amended to read as follows:

38. "Wholesaler" means a person operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs or devices, medicinal chemicals, medicines, or poisons are sold, manufactured, compounded, dispensed, stocked, exposed, distributed from, or offered for sale at wholesale in this state. "Wholesaler" does not include those wholesalers who sell only proprietary or over=the=counter medicines. "Wholesaler" also does not include a commercial carrier that temporarily stores prescription drugs or devices, medicinal chemicals, medicines, or poisons while in transit.

Sec. ___. Section 155A.4, subsection 2, paragraph a, Code 2005, is amended to read as follows:

a. A ~~manufacturer or~~ wholesaler to distribute prescription drugs or devices as provided by state or federal law.

Sec. ___. Section 155A.13, subsection 6, unnumbered paragraph 1, Code 2005, is amended to read as follows:

To qualify for a pharmacy license, the applicant

shall submit to the board a license fee as determined by the board and a completed application on a form prescribed by the board ~~that shall include the following information and~~. The application shall include the following and such other information as required by rules of the board and shall be given under oath:

Sec. ___. Section 155A.17, subsection 2, Code 2005, is amended to read as follows:

2. The board shall establish standards for drug wholesaler licensure and may define specific types of wholesaler licenses. The board may deny, suspend, or revoke a drug wholesale license for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States relating to prescription drugs, devices, or controlled substances, or for a violation of this chapter, chapter 124, 124A, 124B, 126, or 205, or a rule of the board.

Sec. ___. Section 155A.17, subsection 3, Code 2005, is amended to read as follows:

3. The board shall adopt rules pursuant to chapter 17A on matters pertaining to the issuance of a wholesale drug license. The rules shall provide for conditions of licensure, compliance standards, licensure fees, disciplinary action, and other relevant matters. Additionally, the rules shall establish provisions or exceptions for pharmacies, chain pharmacy distribution centers, logistics providers, and other types of wholesalers relating to pedigree requirements, drug or device returns, and other related matters, so as not to prevent or interfere with usual, customary, and necessary business activities.

Sec. ___. Section 155A.19, subsection 1, paragraph f, Code 2005, is amended by striking the paragraph and inserting in lieu thereof the following:

f. Change of legal name or doing=business=as name.

Sec. ___. Section 155A.19, Code 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 3. A wholesaler shall report in writing to the board, pursuant to its rules, the following:

a. Permanent closing or discontinuation of wholesale distributions into this state.

b. Change of ownership.

c. Change of location.

d. Change of the wholesaler's responsible individual.

e. Change of legal name or doing=business=as name.

f. Theft or significant loss of any controlled substance on discovery of the theft or loss.

g. Disasters, accidents, and emergencies that may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, and disease.

h. Other information or activities as required by rule.

Sec. ___. Section 155A.20, subsection 1, Code 2005, is amended to read as follows:

1. A person, other than a pharmacy or wholesaler licensed under this chapter, shall not display in or on any store, internet site, or place of business, nor use in any advertising or promotional literature, communication, or representation, the word or words: "apothecary", "drug", "drug store", or "pharmacy", either in English or any other language, any other word or combination of words of the same or similar meaning, or any graphic representation in a manner that would mislead the public ~~unless it is a pharmacy or drug wholesaler licensed under this chapter~~.

Sec. ___. Section 155A.21, Code 2005, is amended to read as follows:

155A.21 UNLAWFUL POSSESSION OF PRESCRIPTION DRUG OR DEVICE == PENALTY.

1. A person found in possession of a drug or device limited to dispensation by prescription, unless the drug or device was so lawfully dispensed, commits a serious misdemeanor.

2. Subsection 1 does not apply to a licensed

pharmacy, licensed wholesaler, physician, veterinarian, dentist, podiatric physician, therapeutically certified optometrist, advanced registered nurse practitioner, physician assistant, a nurse acting under the direction of a physician, or the board of pharmacy examiners, its officers, agents, inspectors, and representatives, nor to a common carrier, manufacturer's representative, or messenger when transporting the drug or device in the same unbroken package in which the drug or device was delivered to that person for transportation.

Sec. ___. Section 155A.23, Code 2005, is amended to read as follows:

155A.23 PROHIBITED ACTS.

A person shall not perform or cause the performance of or aid and abet any of the following acts:

1. ~~Obtain or attempt~~ Obtaining or attempting to obtain a prescription drug or device or ~~procure or attempt~~ procuring or attempting to procure the administration of a prescription drug or device by:

a. ~~Fraud~~ Engaging in fraud, deceit, misrepresentation, or subterfuge.

b. ~~Forgery or alteration of~~ Forging or altering a written, electronic, or facsimile prescription or ~~of~~ any written, electronic, or facsimile order.

c. ~~Concealment of~~ Concealing a material fact.

d. ~~Use of~~ Using a false name or ~~the~~ giving ~~of~~ a false address.

2. Willfully ~~make~~ making a false statement in any prescription, report, or record required by this chapter.

3. For the purpose of obtaining a prescription drug or device, falsely ~~assume~~ assuming the title of or ~~claim~~ claiming to be a manufacturer, wholesaler, pharmacist, pharmacy owner, physician, dentist, podiatric physician, veterinarian, or other authorized person.

4. ~~Make or utter~~ Making or uttering any false or forged oral, written, electronic, or facsimile prescription or oral, written, electronic, or facsimile order.

5. ~~Affix any false or forged label to a package or receptacle containing prescription drugs~~ Forging, counterfeiting, simulating, or falsely representing any drug or device without the authority of the manufacturer, or using any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.

6. Manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or that has otherwise been rendered unfit for distribution.

7. Adulterating, misbranding, or counterfeiting any drug or device.

8. Receiving any drug or device that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and delivering or proffering delivery of such drug or device for pay or otherwise.

9. Adulterating, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or device or committing any other act with respect to a drug or device that results in the drug or device being misbranded.

10. Purchasing or receiving a drug or device from a person who is not licensed to distribute the drug or device to that purchaser or recipient.

11. Selling or transferring a drug or device to a person who is not authorized under the law of the jurisdiction in which the person receives the drug or device to purchase or possess the drug or device from the person selling or transferring the drug or device.

12. Failing to maintain or provide records as required by this chapter, chapter 124, or rules of the board.

13. Providing the board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the scope of this chapter, chapter 124, or rules of the

board.

14. Distributing at wholesale any drug or device that meets any of the following conditions:

a. The drug or device was purchased by a public or private hospital or other health care entity.

b. The drug or device was donated or supplied at a reduced price to a charitable organization.

c. The drug or device was purchased from a person not licensed to distribute the drug or device.

d. The drug or device was stolen or obtained by fraud or deceit.

15. Failing to obtain a license or operating without a valid license when a license is required pursuant to this chapter or chapter 147.

16. Engaging in misrepresentation or fraud in the distribution of a drug or device.

17. Distributing a drug or device to a patient without a prescription drug order or medication order from a practitioner licensed by law to use or prescribe the drug or device.

18. Distributing a drug or device that was previously dispensed by a pharmacy or distributed by a practitioner except as provided by rules of the board.

19. Failing to report any prohibited act.

Information communicated to a physician in an unlawful effort to procure a prescription drug or device or to procure the administration of a prescription drug shall not be deemed a privileged communication.

Subsections 6 and 7 shall not apply to the wholesale distribution by a manufacturer of a prescription drug or device that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

Sec. ___. Section 155A.24, Code 2005, is amended to read as follows:

155A.24 PENALTIES.

1. ~~A~~ Except as otherwise provided in this section, a person who violates a provision of section 155A.23 or who sells or offers for sale, gives away, or administers to another person any prescription drug or device in violation of this chapter commits a public offense and shall be punished as follows:

a. If the prescription drug is a controlled substance, the person shall be punished pursuant to ~~section 124.401, subsection 1, and section 124.411~~ chapter 124, division IV.

b. If the prescription drug is not a controlled substance, the person, upon conviction of a first offense, is guilty of a serious misdemeanor. For a second offense, or if in case of a first offense the offender previously has been convicted of any violation of the laws of the United States or of any state, territory, or district thereof relating to prescription drugs or devices, the offender is guilty of an aggravated misdemeanor. For a third or subsequent offense or if in the case of a second offense the offender previously has been convicted two or more times in the aggregate of any violation of the laws of the United States or of any state, territory, or district thereof relating to prescription drugs or devices, the offender is guilty of a class "D" felony.

2. A person who violates any provision of this chapter by selling, giving away, or administering any prescription drug or device to a minor is guilty of a class "C" felony.

3. A wholesaler who, with intent to defraud or deceive, fails to deliver to another person, when required by rules of the board, complete and accurate pedigree concerning a drug prior to transferring the drug to another person is guilty of a class "C" felony.

4. A wholesaler who, with intent to defraud or deceive, fails to acquire, when required by rules of the board, complete and accurate pedigree concerning a drug prior to obtaining the drug from another person is guilty of a class "C" felony.

5. A wholesaler who knowingly destroys, alters, conceals, or fails to maintain, as required by rules of the board, complete and accurate pedigree concerning any drug in the person's possession is

guilty of a class "C" felony.

6. A wholesaler who is in possession of pedigree documents required by rules of the board, and who knowingly fails to authenticate the matters contained in the documents as required, and who nevertheless distributes or attempts to further distribute drugs is guilty of a class "C" felony.

7. A wholesaler who, with intent to defraud or deceive, falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of drugs or devices is guilty of a class "C" felony.

8. A wholesaler who knowingly forges, counterfeits, or falsely creates any pedigree, who falsely represents any factual matter contained in any pedigree, or who knowingly omits to record material information required to be recorded in a pedigree is guilty of a class "C" felony.

9. A wholesaler who knowingly purchases or receives drugs or devices from a person not authorized to distribute drugs or devices in wholesale distribution is guilty of a class "C" felony.

10. A wholesaler who knowingly sells, barters, brokers, or transfers a drug or device to a person not authorized to purchase the drug or device under the jurisdiction in which the person receives the drug or device in a wholesale distribution is guilty of a class "C" felony.

11. A person who knowingly manufacturers, sells, or delivers, or who possesses with intent to sell or deliver, a counterfeit, misbranded, or adulterated drug or device is guilty of the following:

a. If the person manufactures or produces a counterfeit, misbranded, or adulterated drug or device; or if the quantity of a counterfeit, misbranded, or adulterated drug or device being sold, delivered, or possessed with intent to sell or deliver exceeds one thousand units or dosages; or if the violation is a third or subsequent violation of this subsection, the person is guilty of a class "C" felony.

b. If the quantity of a counterfeit, misbranded, or adulterated drug or device being sold, delivered, or possessed with intent to sell or deliver exceeds one hundred units or dosages but does not exceed one thousand units or dosages; or if the violation is a second or subsequent violation of this subsection, the person is guilty of a class "D" felony.

c. All other violations of this subsection shall constitute an aggravated misdemeanor.

12. A person who knowingly forges, counterfeits, or falsely creates any label for a drug or device or who falsely represents any factual matter contained on any label of a drug or device is guilty of a class "C" felony.

13. A person who knowingly possesses, purchases, or brings into the state a counterfeit, misbranded, or adulterated drug or device is guilty of the following:

a. If the quantity of a counterfeit, misbranded, or adulterated drug or device being possessed, purchased, or brought into the state exceeds one hundred units or dosages; or if the violation is a second or subsequent violation of this subsection, the person is guilty of a class "D" felony.

b. All other violations of this subsection shall constitute an aggravated misdemeanor.

14. This section does not prevent a licensed practitioner of medicine, dentistry, podiatry, nursing, veterinary medicine, optometry, or pharmacy from acts necessary in the ethical and legal performance of the practitioner's profession.

15. Subsections 1 and 2 shall not apply to a parent or legal guardian administering, in good faith, a prescription drug or device to a child of the parent or a child for whom the individual is designated a legal guardian.

Sec. ___. NEW SECTION. 155A.40 CRIMINAL HISTORY RECORD CHECKS.

1. The board may request and obtain, notwithstanding section 692.2, subsection 5, criminal history data for any applicant for an initial or

renewal license or registration issued pursuant to this chapter or chapter 147, any applicant for reinstatement of a license or registration issued pursuant to this chapter or chapter 147, or any licensee or registrant who is being monitored as a result of a board order or agreement resolving an administrative disciplinary action, for the purpose of evaluating the applicant's, licensee's, or registrant's eligibility for licensure, registration, or suitability for continued practice of the profession. Criminal history data may be requested for all owners, managers, and principal employees of a pharmacy or drug wholesaler licensed pursuant to this chapter. The board shall adopt rules pursuant to chapter 17A to implement this section. The board shall inform the applicant, licensee, or registrant of the criminal history requirement and obtain a signed waiver from the applicant, licensee, or registrant prior to submitting a criminal history data request.

2. A request for criminal history data shall be submitted to the department of public safety, division of criminal investigation and bureau of identification, pursuant to section 692.2, subsection 1. The board may also require such applicants, licensees, and registrants to provide a full set of fingerprints, in a form and manner prescribed by the board. Such fingerprints may be submitted to the federal bureau of investigation through the state criminal history repository for a national criminal history check. The board may authorize alternate methods or sources for obtaining criminal history record information. The board may, in addition to any other fees, charge and collect such amounts as may be incurred by the board, the department of public safety, or the federal bureau of investigation in obtaining criminal history information. Amounts collected shall be considered repayment receipts as defined in section 8.2.

3. Criminal history information relating to an applicant, licensee, or registrant obtained by the board pursuant to this section is confidential. The board may, however, use such information in a license or registration denial proceeding. In a disciplinary proceeding, such information shall constitute investigative information under section 272C.6, subsection 4, and may be used only for purposes consistent with that section.

4. This section shall not apply to a manufacturer of a prescription drug or device that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

Sec. ___. NEW SECTION. 155A.41 CONTINUOUS QUALITY IMPROVEMENT PROGRAM.

1. Each licensed pharmacy shall implement or participate in a continuous quality improvement program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors and for improving patient use of medications and patient care services. Under the program, each pharmacy shall assess its practices and identify areas for quality improvement.

2. The board shall adopt rules for the administration of a continuous quality improvement program. The rules shall address all of the following:

a. Program requirements and procedures.

b. Program record and reporting requirements.

c. Any other provisions necessary for the administration of a program.>

#2. By renumbering as necessary.

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JEFF ANGELO

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ROBERT E. DVORSKY

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JEFF LAMBERTI

_____

STEVEN H. WARNSTADT

_____

JOE BOLKCOM

_____

CHARLES W. LARSON, JR.

_____

JEFF DANIELSON
KEITH A. KREIMAN
HF 882.325 81
rn/cf/4935